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EP 0 565 542 B1 formation

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(12)

(45) Date of publication and mention of the grant of the patent: 21.08.1996 Bulletin 1996/34

(21) Application number: 92901189.8

(22) Date of filing: 22.11.1991

m # d. from == (51) Int. Cl.6: A61F 2/06

SPECIFICATION

(86) International application number: PCT/US91/08587

(87) International publication number: WO 92/11824 (23.07.1992 Gazette 1992/19)

(54) RESECTABLE SELF-EXPANDING STENT ... 5 Feb.

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(84) Designated Contracting States: AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: 04.01.1991 US 637356

(43) Date of publication of application: 20.10.1993 Bulletin 1993/42

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sue involved floes nothis specification truct urine flow. to the first of and it of the early compared by the

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and the first of t diameter and that it remain stable at that diameter over... an extended period to provide the necessary support for = 0.2 inhibiting the urethra from again collapsing. Various 145 mend which confinues to a devices having this property are described in the patent, art. For example, in U.S. Patent No. 4,655,771 to Walf-P sten, and in fig.-A-1602510 and PR-A-2025090 there is the CA figither object of the described a lubular stent formed from braided metalics brightnistent fabricated from a wire which, when stretched longitudinally, will assume a hise salf-expending randula relatively small diameter, but when it is allows to spring aa kala a sir In length, an all chair his rase in the

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Life and to ef

Description

Background of the Invention

preamble of Claim 1. Such a stent is known e.g. from: FR-A-1602513. Stent devices of this type are intended to be inserted in tubular body organs for maintaining the organ in a patent condition. The invention refers more particularly to the design of a tubular stent whose thermoplastic material and geometry allow it to expand by itself from a radially compressed condition to a larger diameter and which can later be resected using an electrosurgical instrument.

for maintaining a tubular body organ, such as a vein, and involved to the appropriate site in the fubular organ where artery, bile duct, fallopian tube or urethra, in a patent? Stiffle stent is to be deployed. The stent is made from a condition whereby body fluids can continue to flow in a real realizable metal so that when the balloon is inflated, it normal fashion. Consider the condition termed bentignated inswill stretch the walls of the stent, creating an open lattice and bentignated inswill stretch the walls of the stent, creating an open lattice. prostatic hypertrophy where, in the male urinary sys- 2000 pattern. When the balloon is again deflated; the stent tem, with age, the prostate gland may swell. If the urethra which the gland surrounds is collapsed to the point and the dilatation catheter can again be where the flow or urine from the bladder becomes particle withdrawn from the body. tially or even fully blocked, surgical intervention is often The stent arrangement described in the Rosenbluth instrument called a resectoscope.

an important characteristic that it possess a low cross and subbidy or gath attacking it deemed necessary. back to a shorter length, an attendant increase in the saliminstrument by the saliminstrume diameter takes place. These devices suffer from a him electronic light from the light and the light from the light and the light from the lig number of practical problems, not the least of which is the difficulty in properly positioning the stent so that, when released, it will collapse longitudinally and increase in size radially to the point where patency is established along the length of the prostate without having a portion of the stent protrude into the external

sphincter so as to result in urinary incontinence or, alternatively, into the bladder where it would serve as a nidus a side welforstonelformation is of specied openings -

from T is a greatly or '

defined by straigh, it a stent of the type described in the wallsten reli-expanding tribular This invention relates to a stent according to the men patent remains and the body application of several the present invention, 19 months; fissue ingrowth occurs and the stent, because 179 2 is a high of of its open construction, becomes incorporated into the vessel wall where it is shielded from the urine. However, should it become necessary to explant the stent for any 10 reason, it becomes extremely difficult to remove it through the urethra.

US Patent 4,893,623 (to Rosenbluth) describes a tubular stent where the wall of the tube is slift in a predetermined fashion. To implant the stent, it is mounted Various forms of surgical stents are known in the art -- 15 over a deflated balloon on a dilatation catheter and then will remain stretched to the diameter established by the

required. In surgically addressing this problem hards after patent also becomes difficult to remove once tissue of a complex of transurethral resection of the prostate is often perse whering rowth thas occurred Moreover, sit is not self-expand-y in formation and formed in which portions of the prostate gland areas of aing-but sinstead, smust be stretched to a desired diametry become set in the content shaved or resected away using an electrosurgicals to beter through the capplication of an foutward radial force the street electrosurgicals to beter through the capplication of an foutward radial force the street electrosurgicals. diameter iWherighat outside force isiremoved; the stent does not thread-life stripe as a Another approach in treating an enlarged prostate color provide a residual outward radial force against the ves- The material from the involves inserting a dilatation catheter into the urethraformly seli/wallovThisomay/cleadoto undesired/migration of the a Promopilabile in a and advancing that catheter until the balloon portion-determitent within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the balloon portion-determined within the hollow vessel subsequent to its implantification of the catheter until the catheter until the balloon portion determined within the hollow vessel subsequent to its implantification of the catheter until the c thereof is aligned with the prostate. Then the balloon is save station and prior to the establishment of tissue ingrowth respectively. inflated to stretch and enlarge the urethra. Another is settled It is accordingly a principal object of the present these completes treatment involves the insertion of a stent which function invention ito provide an improved tubular stent for use in the look of the th tions to re-enforce the urethra at the site so that the tisevented the lument of a tubulation of body organise ingrowth in the discussions. sue involved does not collapse to obstruct urine flowaccurs. A partiAriother object of the virvention is to provide a tubor dulus of classicity and Where a stent is to be implanted transurethrally, it is a firstent which may readily be resected from a tubular from the control of the contr inon. For example, my. sectional profile to facilitate its being routed to them 40 tasks Netianothersobject of the invention is 100 previderand, but DELRING. desired site within the urethra. Once appropriately posi-21/4 fireself-expanding-fubular stentil which his loagable of being a Corporation, here tioned, it is desirable that the stent expand to a largern, the finserted through the humanisof actubulantoody lorgan. Verious ment of diameter and that it remain stable at that diameter overm a lawfile dexhibiting deschala diameter, douthwhich is selly principle, stentile. an extended period to provide the necessary support for = d //expanding/typon/beingenelleased/from dts linsertion (tooh) typos have been inhibiting the urethra from again collapsing. Various determand/which continues to exert a residual outward radial while a solid tube of devices having this property are described in the patent; read force against the reset wallator maintain the stentain the stentain the stentain the stentain to the stentain t art. For example, in U.S. Patent No. 4,655,771 to Wallet as theplaceum of oregin encountered. sten, and in FR-A-1602513 and FR-A-2525896 there is the feature object of the invention is to provide a tubus of a plurality of line described a tubular stent formed from braided metalmattinglaristent tabricated from a theirmoplastic material, which thombic effortunes wire which, when stretched longitudinally, will assume aention visil iself-expanding and it which disc capable't of obeing grally joined at 4000 relatively small diameter, but when it is allows to spring native fesected by being outsinto pieces with an electrosurgical signification in

Summary of the invention

According to the present invention, there is provided a stent for insertion into a tubular organ for maintaining the organ patent, comprising a single-piece tubular member consisting of a non-braided web or

1 -

mesh formed into a closed tube of continuous section and without any overlapping longitudinal edges, having ter to a smaller diameter and which tubular member self-expands when the radial compressive force is 10removed, characterized in that said strands are intersecting strands integrally joined together at their points ... Fig. 4 is a side elevation view of the stent of Figure producing relative movement of said strands at said as said as side elevation view of a stent according to the points of intersection or a significant change in axial 15. Invention having as pattern of apertures whose in a significant change in axial 15. length of said tubular member. It is preferably fabricated . പ്രസം പ്രസം enhances the self-expanding characteristics വര്ദ്ദാ പ്രവാധിനാ from a thermoplastic material, allowing same to be a median of the devices matter at the tubular control of the devices material. shaved or resected into smaller pieces for later removals, in Figure 4, is ideal@act by constrail 24. should that become necessary. By controlling the electricities a Detailed Description of the Univertion; trical conductivity of the thermoplastic material so that it \$20 \tag{60 \tag{

thermoplastic resin, whose radial thickness is about 1/1/25 1/495 sused, (but DELRIN® plastic, iravailable through the Du

from the following detailed description of appreferredak of aparticulant limitation eintended a each of the individual the several views refer to corresponding parts.

Brief Description of the Drawings

a side wall exhibiting a pattern of spaced openings have to IFig. 11 six angreative enlarged perspective view of animatics. defined by strands, said tubular member having asintree the clanself-expanding tubular stemp (not in accordance with ermoplastic im.). ole-plane_fenestrated side wall, with said_side;_wall-preserved whe present/invention; but included to illustrate it) to the material, its: including a pattern of regular generally eye-shaped cut-; attituding Figt.2 is a side elevation view of the stent of Figure parents in that of member to be radially compressed from a larger diame. is its loaded into the stent delivery device;

Fig. 3 is a side devation view of the stent of Figure 1 when radially compressed for insertion into the

approximates that of human tissue, the ability to resect ______ With reference to Figure 1, a self-expanding intraluthe stent using an electrosurgical instrument is a minal prosthesis or stent is identified generally by mumeral 100 and is seen to include a generally tubular in the control of the cont The stent of the present invention comprises a non-time member 12 having a pair of opposed ends 14 and 16 braided thermoplastic web or mesh formed into a closed 9:25, Hand a fenestrated wall-sufface 189. The stent of Figure 1:49-44 to 1905, 100 tube where the web or mesh includes a pattern of agernst the may be formed in a molding operation of alternatively effect of specific tures of a predetermined shape that allows the cost maintainally be created from a solid tube by laser or water jet), paid tube last un tube to be radially compressed from a relatively larger soy of cutting the pattern of apertures so as to leave intersectivated side well a diameter to a significantly smaller diameter when subjety disjngsthread-like strips asiaty 20 and 22 therebetween attern of regular acjected to inward radially directed compressive forces between porthermaterial from which the stent 10% formed may a said spaced or uniformly applied over its surface, but which returns to acting the becanthermoplastic thaving a high modulus of elasticity or to be raction, predetermined intermediate diameter when those comey reclaisught that when littles subjected to inwardly directed fadial tention and an employer pressive forces are removed. The intermediate diamety priorforces uniformly applied over its surface, it will collapse or self-expensive ter is sufficiently large to assure continuing outwards, which to allesser, diameter, but other spring back when the same services force against the lumen wall. This tends to prevent mash radial compressive forces are removed. At variety inforces will be sufficient to the second of the unwanted migration prior to the time that tissue ingrowther a rmedical-grade plastics are available which exhibit a highwints of inference occurs. A particularly efficacious device has been found than the modulus of lefasticity and which may be employed in tabexpansion not proto result with a pattern of openings defined by thin to no ricating the self-expanding stents of the present inventional and the self-expanding stents of the self-expanding strands of DELRIN® plastic, an acetal homopolymerinto thation. For example, inylon on a sputable polyester may be hange in exial to to 21/4 times their circumferential width. Withathis pat-of stres Point Corporation; has been found to be quite suitable stent according to a tern, the fenestrated tube may be radially compressed where the Various analytical uning methods are available force is formed from from a larger diameter, d1, to a smallertidiameterigs as sfabricating dheastent fing accordance with this invertionnatorial, corid c d₂ = d₁/4. The ability of the stent to spring/backito embodin Repototypes shaves do each produced hey mappropriately the predetermined outer diameter depends (upon the office mounting a solid tube of DELIRIN® plasticion a mandretermine according to degree of plastic deformation that the material incurs ascentiationd theris using saylaber, the fenestrations or apertures locally resectables well as the amount of creep encountered. The specifies care cut through the thickness dimension of the wall to provide the The features and advantages as well as the methodas thou formial plurality of intersecting strands creating contigutent flooriding it. of making and using the tubular stent of the present pening ous whom bics apertures in The Lintersecting is tands derenated tall is an exinvention will become apparent to those skilled in the artis soci-integrally joined at their points of Intersection. With mo resin. embodiment, especially when considered in conjunction this this trands 20): 22-may-be 0:38 mm. (0:015 in) thick limited and according to with the accompanying drawings in which numerals in, they radial direction and 0.25mm (0.010 in) wide in the cire in the cumferential direction. The laser may be computer-con-

> definition. In a production setting, it is contemplated that the stents of the present invention may be formed in a molds :::/

55 trolled insuring accurate spacing and precise line

ing operation which results in very low-cost production in comparison to the laser cutting method.

Referring next to Figures 2 through 4, at the time of. manufacture, the diameter of the stent 10 is purposely oversized compared to the size of the lumen in which it is intended ultimately to be implanted. For example, it may be designed to initially have an outside diameter, D₁, as shown in Figure 2. Prior to insertion into the lumen of the hollow body organ to be supported, the stent of Figure 2 is radially compressed into an insertion tool and will collapse as shown in Figure 3 to exhibit a significantly lower diameter, D2. When the tool and stent have been routed through the body lumen to the location where the stent is to be placed, it is released from the tool and allowed to expand to a diameter, D3, which is less than diameter, D₁, (due to plastic deformation) and thereby provides support to the walls of the tubular organ which, in Figure 4, is identified by numeral 24.

While collapsing the stent to its smallest diameter, D₂, (Figure 3) results in some measure of plastic deformation, by originally over-sizing the stent as shown in Figure 2, it is capable of self-expansion to a working diameter, D3, as shown in Figure 4. In fact, the stent is preferably designed such that when in position within the body organ, it will continue to exert a slight outward force against the internal wans of the body organ, thus tending to maintain the stent in position and reducing the tendency of the stent to migrate. Alternatively, appropriately disposed, radially-projecting finger-like barbs may be incorporated to resist such migration. 2.

By loading the stent of Figure 2 into its insertion tool and thereby reducing its size to that shown in Figure 3, immediately prior to the implantation thereof, creep deformation, which is time dependent, is minimized. 3.

In the stent shown in Figure 1, the openings areshaped like a rhombus. Good results have been achieved when the acute angles thereof are in the range of from 40° to 60° such that the corresponding obtuse. angles fall into the range of from 140° to 120° Computer analysis has shown that this shape results in a concentration of stress forces at the points of intersection of the strands where they are integrally joined. By shaping. the openings as shown in the stent of Figure 5 which is the only embodiment of those described here which forms part of the present invention as claimed, the stress concentration points are significantly reduced. The apertures or openings in Figure 5 may be 95 nact Anspruch 1, wobeing Sirange one described as those which result when the strands defining those openings have a sinusoidal pattern and where the negative peaks of a first strand integrally join to the positive peak of an adjacent strand. Because the aperavehdications tures resemble the eye opening of a human, for ease of description, they are referred to herein as eye-shaped. apertures. Because the intersecting strands are integrally joined at their points of intersection, the opposed ends of the stent are free of sharp points which occur when a braided tube structure of the type disclosed in the Wallsten patent is cut to a desired length. Hence,

the stent of the present invention is less traumatic to tissue at the time of its implantation.

Stant (B) forming the stant of the present invention from a Organitable the moplastic material and by introducing an 5 in additive to the material; its electrical conductivity can be and made comparable to that of the tissue in which the stent will become embedded. Should it become necessary or desirable to later remove the stent device, an appropriate electrosurgical instrument may be used to cut through both the involved tissue and the stent material so that the pieces resulting can be withdrawn through the body lumen in which the stent had-been positioned. The fact that the conductivity of the tissue and the stent material are approximately the same results in greater is uniformity and control of the electrosurgical current as with the resection takes place Chinage ... Showing 59 dale don Burnitarrian Stampet was bings 195. 🗢

ລືວາເ**Claims** ແລວວອ້ອງໄກນ ເກົດວາກໃຕ້ປູ່ໃນຂາວວິດເລີຍເຄືອກເຮັ້

por mind to a contract that a contract the literature 20 1. A stent (10) for insertion into a tubular organ for ler. For maintaining the organ patent, comprising a singlegrisere piece tubular member (12) consisting of a non-Strang braided web or mesh formed into a closed tube of continuos section and without any overlapping 25 on unclongitudinal edges; having a side wall (18) exhibit. Beweguing a pattern of spaced openings defined by strands oder zu (20,22) i said tubular member having a single-plane senland fenestrated side wall with said side wall including a pattern of regular generally eye-shaped cut-outs 30 ieni naforming said spaced topenings to allow said tubular. Elementmembereto beiradially/compressed/from-a larger ren Maladiameteridotassmaller diameter and which tubular member self-expands when the radial compressive Signi inforce is removed, characterized in that said strands 35/sch reare intersecting strands integrally joined together at ... Material their points of intersection, the compression and later expansion not producing relative movement of Start presaid strands at Said points of intersection or a signif-Majerial icant change in axial length of said tubular member.

2. The stent according to claim 1, wherein said tubular Signi namen/bergs.formed from an electrosurdically resectaisch relable materialiaterial eine elektrische Leitfä-

≓fΩrkeit aufweist, die derienigen 450m3erg@hrelistenthaccording.to claim 2, wherein said electrosurgically resectable material is a thermoplastic.

, radidle The stent according to claim 3, wherein said resectthrer Broadleumaterial is an acetal homopolymer thermoplastic resin.

- 5. The stent according to claim 2, wherein said electrosurgically résectable material has an electrical conductivity approximately that of body tissue.
 - -6. The stent according to claim 1, wherein said strands have radial thickness in the range of from 11/4 to 21/4 times their width: 人名英格特特拉 医结节 医自动强制 医动脉

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Dileteten volor: เดียร brine ont เก 11/4 à 21/4 fois let :

Patentansprüche

- 1. Stent (10) zur Insertion in ein röhrenförmiges Organ, um das Organ durchgängig zu halten, der ein einstückiges, röhrenförmiges, aus einem nicht umflochtenen, zu einem geschlossenen Tubus eines fortlaufenden Bereichs gebildeten Netz oder Mesh ohne jegliche in Längsrichtung verlaufende überlappende Kante bestehendes Element (12) mit einer Seitenwand (18) mit einem Muster aus durch die Stränge (20, 22) festgelegten beabstandeten Öffnungen umfaßt, wobei das röhrenförmige Element eine einzelne Ebene aufweisende fenestrierte Seitenwand, die ein Muster aus regulären. im allgemeinen in Augenform ausgeformten Ausschnitten, die die beabstandeten Öffnungen bilden, so daß das röhrenförmige Element von einem grö-Beren Durchmesser zu einem kleineren Durchmesser radial zusammengedrückt werden kann, umfaßt, aufweist und sich bei Entfernen der radia-Ien Kompressionskraft selbst ausdehnt, dadurch gekennzeichnet, daß die Stränge sich kreuzende Stränge sind, die miteinander an ihren Kreuzungspunkten integral verbunden sind und die Kompression und spätere Expansion nicht zu einer relativen Bewegung der Stränge an den Kreuzungspunkten oder zu einer signifikanten Veränderung der Achsenlänge des röhrenförmigen Elements führen.
- 2. Stent nach Anspruch 1, wobei das röhrenförmige Element aus einem elektrochirurgisch resektierbaren Material gebildet ist.
- Stent nach Anspruch 2, wobei das elektrochirurgisch resektierbare Material ein thermoplastisches Material ist.
- Stent nach Anspruch 3, wobei das resektierbare Material ein thermoplastisches Acetalhomopolymerharz ist.
- Stent nach Anspruch 2, wobei das elektrochirurgisch resektierbare Material eine elektrische Leitfänigkeit aufweist, die derjenigen des Körpergewebes etwa gleicht.
- 6. Stent nach Anspruch 1, wobei die Stränge eine radiale Dicke im Bereich des 11/4- bis 21/4fachen ihrer Breite aufweisen.

Revendications

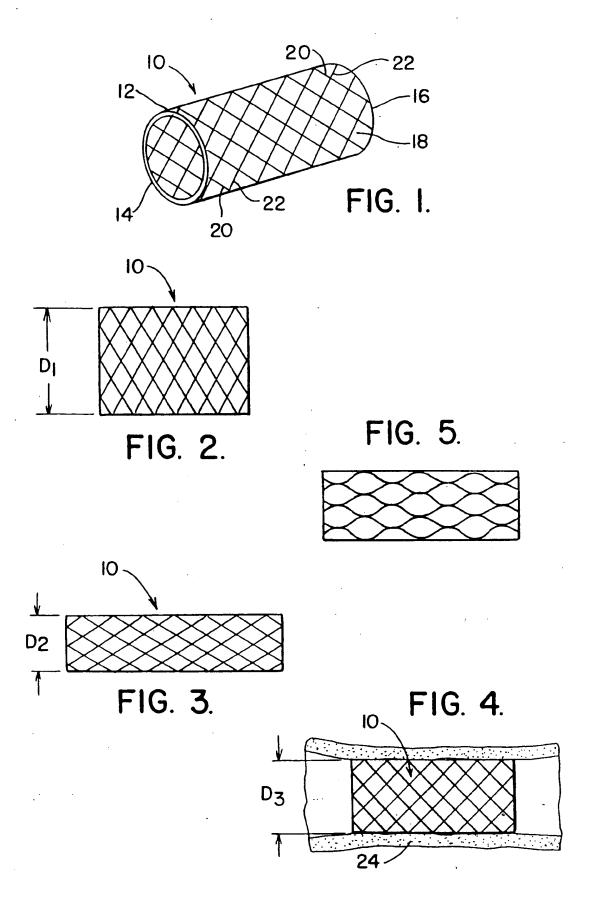
Dilatateur (10) destiné à être introduit dans un organe tubulaire pour maintenir l'organe inobstrué, comprenant un élément tubulaire monobloc (12) consistant en une trame ou un treillis non tressé, réalisé dans un tube fermé de section continue et sans bords longitudinaux qui se chevauchent, comportant une paroi latérale (18) présentant un motif

de trous distance les uns des autres, délimités par des brins (20, 22), ledit élément tubulaire ayant une paroi latérale située dans un plan unique, comportant des fenêtres, ladite paroi latérale comprénant un motif de découpes régulières, sensiblement en forme d'oeil, formant lesdits trous espacés pour permettre audit élément tubulaire d'être comprimé radialement d'un grand diamètre à un diamètre plus petit et ledit élément tubulaire subissant une autôexpansion lorsque la force radiate de compression, de est supprimée, caractérisé en ce que lesdits brins sont des brins qui forment des points d'intersection, qui sont reliés monobloc à leurs points d'intersection, la compression et l'expansion ultérieure ne produisant aucun mouvement relatif desdits brins auxdits points d'intersection ni une modification notable de la longueur axiale dudit élément tubulaire : ...

- 2. Dilatateur selon la revendication 1, dans lequel ledit élément tubulaire est réalisé en une matière capable de subir une résection par voie électrochirurgicale.
- 3. Dilatateur selon la revendication 2, dans lequel ladite matière capable de subir une résection par voie électrochirurgicale est une matière thermoplastique.
 - 4. Dilatateur selon la revendication 3, dans lequel ladite matière capable de subir une résection est une résine thermoplastique à base d'un homopolymère d'acétal.
 - Dilatateur selon la revendication 2, dans lequel ladite matière capable de subir une résection par voie électrochirurgicale a une conductivité électrique qui est approximativement celle du tissu du corps.
 - 6. Dilatateur selon la revendication 1, dans lequel lesdits brins ont une épaisseur radiale de l'ordre de 11/4 à 21/4 fois leur largeur.

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